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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/451,641	11/30/1999	Danchen Gao	PC10664	9327

28523 7590 02/17/2011

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
02/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

Office Action Summary	Application No.	Applicant(s)	
	09/451,641	GAO ET AL.	
	Examiner	Art Unit	
	S. TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-50,72-75,84,86-90 and 95-153* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-50,72-75,84,86-90 and 95-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/17/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 1-10, 12-50, 72-75, 84, 86-90 and 95-153 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that the present specification does not provide support for the limitations "wherein HPC is not adsorbed on said particulate celecoxib", "wherein said particulate celecoxib is not a composite", and "said particulate is not…comprising hydroxypropylcellulose adsorbed to said particulate celecoxib".

Claims 95-153 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejection because it is not entirely clear what exactly is a "composite particulate". Because the present specification does precisely define the term "composite particulate", and for examining purposes, "celecoxib composite particulate" and "celecoxib particulate" are substantially the same.

Claim Rejections - 35 USC § 103

Claims 1-10, 12-50, 72-75, 84, 86-90 and 95-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Franson et al. US 5,591,456, in view of Black EP 0 863 134 and AAPS Annual Meeting Contributed Papers Abstracts (AAPS).

Franson teaches a dispersible particle comprising crystalline NSAID having hydroxypropyl cellulose adsorbed on the surface thereof in an amount sufficient to maintain an effective average particle size of less than about 1000 nm, and at least 99% of the particle has size less than 400 nm (abstract; and column 3, lines 56 through column 4, lines 1-4).

Franson does not teach the claimed NSAID compound, such as celecoxib.

Black teaches a compound useful as a Cox-2 inhibitor for pain relief, fever and inflammation of a variety symptoms disclosed on page 3, lines 29-36. The compound can be administered orally in the form of tablets, troches, lozenges, or capsules (page 4, lines 1-12). The tablets comprise active ingredient in admixture with excipients, *e.g.*, diluents, disintegrants, binding agents, wetting agents, and surfactant (page 4, lines 15-38). The active agent is present in an amount of 10 to 250 mg. The carrier material may vary from about 5 to about 95% (page 5, lines 39-58). The dosage can be administered once or twice a day, and will provide effective $T_{1/2}$ over a 24 hours period (page 5, lines 22-27). Example 2 discloses the amount of excipients use in a tablet.

Thus, it would have been obvious for one of ordinary skill in the art to modify the NSAID formulation of Franson using the COX-2 compound of Black, because Black teaches a COX-2 compound that is proved useful as an alternative to conventional

NSAIDs (page 3, lines 41-46), because Black teaches COX-2 as a partial or complete substitute for conventional NSAIDs, and because Franson teaches a particle dispersion suitable for a wide variety of active agents including a number of NSAIDs.

Franson further does not teach the claimed properties, such as bioavailability, C_{max}, and T_{max}.

AAPS teaches a celecoxib (Cox-2 inhibitor) formulation that exhibits an unchanged C_{max} value of 1527 and 1077 ng/mL, and a T_{max} of 1.9 hours (see page D32). At page 3469, the AAPS reference teaches a COX-2 composition that is rapidly absorbed with a T_{max} of 1.9 hours, and eliminated with a $t_{1/2}$ of about 15 hours. Accordingly, it would have been obvious to one of ordinary skill in the art to optimize the parameter of Franson in view of Black and AAPS to obtain the claimed properties. This is because AAPS teaches properties of a COX-2 formulation that is useful in pharmaceutical art.

Response to Arguments

Applicant's arguments filed 12/17/10 have been fully considered but they are not persuasive.

Applicant states that the amendment to the claims reciting that “HPC is not adsorbed on said particulate celecoxib” is in accordance with the implied suggestion by the Examiner.

However, to clarify the record, the Examiner does not find in the record of any suggestion as stated by the Applicant.

Applicant argues that Applicants have herein amended the claims by excluding celecoxib particulates wherein HPC is adsorbed on the particulates (see Page 6, line 30-33 of Applicants' corresponding PCT publication WO 00/32189; hereinafter the '189 pub.). Applicants submit that the amended phrase is fully supported. Applicants further submit that the literal basic for such amendment is not required to be found in the specification (the claim phrase need not be *"in haec verba"* in the specification *In Re Wright* 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989); *Crowne Operations, Int'l, Inc. v. Solutia, Inc.,* 289 F.3d 1367, 1376 (Fed. Cir. 2002). Applicants submit that it is well settled that an inventor may excise the prior art from the claim and still satisfy the written description requirement of section 112, first paragraph *In re Johnson,* 194 U.S.P.Q.187 (C.C.P.A. 1977). Thus, it is a perfectly legitimate procedure for an inventor to claim less than the full scope of his disclosure since it is for an inventor to decide what bounds of protection he will seek (see *In re Wertheim* 191 U.S.P.Q. 90 (C.C.P.A. 1976)). See also In re Driscoll 195 U.S.P.Q. 434 CCPA 1977, which cites the following case.

However, in response to the Applicant's arguments, the Examiner notes that Page 6, lines 30-33 of PCT publication WO 00/32189, as directed to by the Applicant, does not expressly disclose the limitation that with respect to the HPC not being adsorbed on the particulate celecoxib. Nonetheless, it is of not that the present application does not claim priority to the PCT publication. Therefore, in the event that the PCT publication does suggest that HPC is not being adsorbed on the particulate celecoxib, this does not provide support for the amendment of the present application.

Further, while the inventor can claim less than the full scope of his disclosure since it is for an inventor to decide what bounds of protection he will seek, specific limitation that requires "HPC is not adsorbed on said particulate celecoxib" is not *less* than the full scope of the disclosure. The only disclosure of HPC in the present specification is directed to a binder. See page 22, line 20. Nowhere in the present specification appear to suggest that the binder cannot adsorb on the particulate celecoxib. Accordingly, the 112, first paragraph rejection is appropriate.

Applicant argues that the primary reference Franson et al., mandates a particle having HPC adsorbed thereon. This is a fundamental difference and it is clear from the quoted passages above from Applicants' specification that Applicants' particles, were they to have HPC adsorbed thereon, would not provide the advantages of Applicants' claimed composition because Applicants' claimed invention advantages are due at least in part to the particulate nature of the celecoxib particles (vs. composite particles). Applicant further states that it has been discovered that milling the celecoxib in an impact mill, such as a pin mill, prior to mixing the celecoxib with excipients to form a composition of the invention, is not only effective in providing improved bioavailability but is also beneficial in overcoming problems associated with the cohesive nature of celecoxib crystals during such mixing or blending. (underline added for emphasis; '189 pub., page 7, lines 12-16).

However, in response to Applicant's arguments with respect t to the present of the HPC, the Examiner notes that although Franson teaches the use of HPC, the

purpose of using HPC is to enhance resistant to gastric irritation. See column 3, lines 49-55. From this, it does not appear that the present of HPC in deed provide any negative effect, such as side-effects, poor bioavailability, and the like. The Examienr is unable to determine any unexpected and/or unusually result between the claimed invention and that of Franson, which teaches the present of HPC. Accordingly, the burden is shifted to applicant to show that the present of HPC would detrimentally affect the desirability for obtaining a composition having high bioavailability. This is because Franson teaches a composition that exhibits the advantageous results desired by the applicant, namely, a high bioavailability. See example 1.

Further, in response to Applicant's arguments that "*it has been discovered that milling the celecoxib in an impact mill, such as a pin mill, prior to mixing the celecoxib with excipients to form a composition of the invention, is not only effective in providing improved bioavailability but is also beneficial in overcoming problems associated with the cohesive nature of celecoxib crystals during such mixing or blending*", Applicant's arguments are not persuasive for the following reasons:

1) the present claims are directed to composition claims, not method claims;

2) the features upon which applicant relies (i.e., milling the celecoxib in an impact mill prior to mixing the celecoxib with excipients) are not recited in the rejected claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993); and

3) as noted above, Franson teaches a celecoxib composition that exhibits the same advantageous results desired by the applicant, namely, a high bioavailability celecoxib formulation.

Further, in response to Applicant's arguments with respect to the celecoxib composite particle, the Examiner is unable to determine any unexpected result especially when the prior art teaches the same advantageous result is being obtained, e.g., a high bioavailability celecoxib formulation.

Applicant argues that Black does not teach the claimed compound celecoxib, rather Black teaches a different COX-2 inhibitor and various compositions thereof. Nowhere does Black describe or suggest the composition of the present invention.

However, in response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the present case, Black is relied upon for the teaching that COX-2 inhibitor is well known as an NSAID. The specific celecoxib is disclosed in the AAPS reference.

Applicant argues that while one could utilize an additional reference (the AAPS reference) which does contain celecoxib, this necessitates the use of three references to arrive at a formulation comprising composite celecoxib, which clearly is not Applicant's claimed invention.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Accordingly, the 103(a) rejection of record is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. TRAN whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. TRAN/
Primary Examiner, Art Unit 1615